K992925

NOV 23 1999

ATTACHMENT 8

510(K) SUMMARY

AX WORKSTATION DR-VIEWER SOFTWARE OPTION

Submitted by:

Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

August 27, 1999

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. **Contact Person:**

Ms. Malgorzata Stanek
Phone: (732) 321-3950 Fax: (732) 321-4841

2. **Device Name and Classification:**

Trade Name:	AX Workstation DR-Viewer Software Option
Classification Name:	Accessory to Angiographic X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1600
Device Class:	Class II
Product Code:	90JAA

3. **Substantial Equivalence:**

The DR-Viewer Software Option is substantially equivalent to the following devices:

Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Philips EasyVision Family Workstation Legs Option	K990455	5/12/99
Philips Spine Option for EasyVision Workstation	K963980	12/23/96

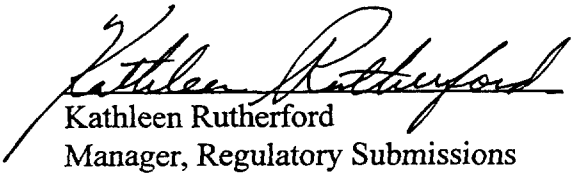
4. **Device Description:**

The DR-Viewer Software Option uses a series of images of the anatomy (i.e. spine, legs, colon) generated with a radiographic, fluoroscopic, or angiographic x-ray system, and reconstructs the images in a single, composite image format. After

reconstruction of the image, the software provides the user with various measurement tools and post-processing functions.

5. **Intended Use of the Device:**
The AX Workstation DR-Viewer Software Option offers the user the ability to visualize composite images of selected anatomy (i.e. spine, legs, colon). The images produced by the package, as well as the measurement tools of DR-Viewer, are intended to assist the physician in diagnosis and treatment of musculoskeletal disorders and gastrointestinal conditions.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
Both the Siemens DR-Viewer Software Option and the Philips EasyVision Workstation Legs Option and Spine Option allow (1) reconstruction of images into a composite image format and (2) post processing of those images.



Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1999

Ms. Malgorzata Stanek
Senior Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Ave. South
Iselin, NJ 08830

Re: K992925
DR-Viewer Software Option for AX Workstation
Dated: August 27, 1999
Received: August 30, 1999
Regulatory class: II
21 CFR 892.1600/Procode: 90 JAA

Dear Ms. Stanek:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 9

INDICATIONS FOR USE

510(k) Number (if known): K992925
Device Name: DR-Viewer

Indications For Use:

The AX Workstation DR-Viewer Software Option offers the user the ability to visualize composite images of selected anatomy (i.e. spine, legs, colon). The images produced by the package, as well as the measurement tools of DR-Viewer, are intended to assist the physician in diagnosis and treatment of musculoskeletal disorders and gastrointestinal conditions.

(Please do not write below this line - continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992925

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)